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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,400	09/11/2003	Kenji Harano	14862Z	5852

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT PAPER NUMBER

3739

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/660,400	Applicant(s) HARANO ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/929,744.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/11/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/929,744, filed on August 14, 2001.

Specification

The disclosure is objected to because of the following informalities: the most current status (i.e. US Patent Number) for the parent application should be provided in applicant's claim for priority in the first sentence of the specification.

Appropriate correction is required.

Claim Objections

Claim 23 is objected to because of the following informalities: in line 9 of claim 23, the phrase "of equal to" should apparently read "is of equal to". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11-18 and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV et al (5,817,093) in view of the teaching of Malis et al (5,318,563).

Williamson, IV et al disclose an electrosurgical system which includes a high frequency current generator (70) for delivering energy to tissue. There is also an output changing means (75/61 – see col. 12, lines 53+) and a control means (79) for controlling the output changing means. There is also a coagulation state judgment means (120) which monitors biomedical information (i.e. current, voltage, impedance) to determine the coagulated state of tissue. Feedback from the judgment means is used by the controller to control the delivery of energy to tissue. With specific regard to claim 23, the Williamson, IV et al system is capable of providing a variety of levels of energy level dependent upon the judged state of tissue coagulation, and Williamson, IV et al further disclose a second or “query” signal which is used to monitor tissue in between bursts of the treatment signal. Williamson, IV et al fail to specifically disclose that each successive power delivery interval is of equal to or shorter duration than an immediate prior interval.

Malis et al teach that it is generally known to delivery RF energy in a series of pulses in order to coagulate tissue. In particular, the pulses of energy (i.e. intermittent delivery of energy) are of uniform width (see Abstract). As such, Malis et al teach that it is known to provide intermittent delivery of RF energy over a plurality of time intervals wherein each successive power delivery time period is equal to (e.g. uniform width bursts) an immediate prior interval. The Malis et al electrosurgical system is substantially analogous to the Williamson, IV et al system in that it monitors tissue parameters, including impedance, to control the output of the generator for tissue coagulation procedures.

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To have provided the Williamson, IV et al system with a generator that provides uniform pulse widths of RF energy for the treatment of tissue would have been an obvious consideration for one of ordinary skill in the art, particularly since Malis et al teach that it is known to use such a pulsed RF system in a feedback controlled coagulation system.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV et al ('093) and Malis et al ('563) and further in view of the teaching of Sherman ('994).

The combination of the Malis et al teaching with Williamson, IV et al has been established. Williamson, IV et al fail to specifically disclose a coagulated state judging means which acquires information during a plurality of pause periods during which output power delivery is discontinued.

Sherman discloses a very similar system, and specifically teaches that the RF output operates on a duty cycle (i.e. cycled on and off periods), and that the impedance of tissue may be monitored during pause or "off" periods. See column 8, lines 19+.

To have provided the Williamson, IV et al system, as modified by the teaching of Malis et al ('563), with a judging means which monitors tissue characteristics during off periods of an electrosurgical generator is deemed to be an obvious modification for one of ordinary skill in the art, particularly since Sherman teaches that duty cycle generators and off-period monitoring are well known in the electrosurgical arena.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 23-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,730,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relative pulse duration for the delivered RF energy is deemed to be an obvious consideration to one of ordinary skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 1-18 and 23-30 have been considered but are moot in view of the new ground(s) of rejection.

In particular, applicant has asserted that the preliminary amendments have overcome the Williamson, IV et al patent and that Williamson, IV et al disclose applying a continuous high-frequency power to power until a predetermined impedance threshold level is reached (applicant's arguments at page 13 of the September 11, 2003 communication). The examiner disagrees with the characterization of the Williamson,

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IV et al system delivering "continuous" high frequency power. Williamson, IV et al admittedly teach providing power until a predetermined impedance threshold is met, at which point RF power is turned off. However, Williamson, IV et al do not specifically state that the power is delivered "continuously". The examiner maintains that most RF electrosurgical systems provide energy to tissue in a series of pulses associated with a duty cycle (i.e. "on" and "off" periods). It is the examiner's assertion that the Williamson, IV et al system probably works on a similar platform, although there is no express disclosure of providing pulsed energy to tissue. Malis et al specifically disclose that it is known to provide energy to tissue as a series of pulses (i.e. intermittently). Moreover, Malis et al teach that the pulse width, or power delivery interval, is uniform for each pulse. It is generally well-known in the art to provide varying duty-cycles to control output parameters of RF electrosurgical systems. As such, the examiner maintains that Malis et al would suggest to one of ordinary skill in the art that it would be obvious to provide the Williamson, IV et al system with a generator that provides uniform pulses of energy to tissue to effect coagulation of the tissue, and the cease delivery of energy when a desired threshold is reached in view of the teaching of Malis et al.

Conclusion

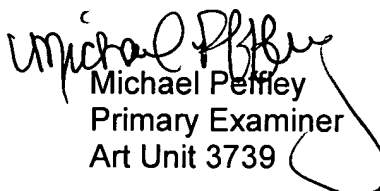
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Buysse et al (6,398,779) disclose a system for applying pulses of energy to tissue to effect coagulation of tissue. Sherman (6,059,778) similarly uses pulsed energy for the treatment of tissue with RF energy. Both of these patents disclose the use of uniform and/or decaying pulse durations.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
September 28, 2005